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10/574,197	03/31/2006	Jean Barthomeuf	BARTHOMEUF1	5887
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624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			NIEBAUER, RONALD T	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)			
	10/574,197	BARTHOMEUF ET AL.			
Office Action Summary	Examiner	Art Unit			
	RONALD T. NIEBAUER	1654			
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address			
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).			
Status					
Responsive to communication(s) filed on <u>28 Not</u> This action is <b>FINAL</b> . 2b)☑ This     Since this application is in condition for alloware closed in accordance with the practice under E	action is non-final. nce except for formal matters, pro				
Disposition of Claims					
4) ☐ Claim(s) 13-26 is/are pending in the application 4a) Of the above claim(s) 22-26 is/are withdraw 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 13-21 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or Application Papers 9) ☐ The specification is objected to by the Examine 10) ☐ The drawing(s) filed on 31 March 2006 is/are: a	rn from consideration.  relection requirement.	o by the Evaminer			
Applicant may not request that any objection to the one Replacement drawing sheet(s) including the correction of the one could be considered to by the Explanation is objected to by the Explanation is objected to by the Explanation is objected.	drawing(s) be held in abeyance. See on is required if the drawing(s) is obj	e 37 CFR 1.85(a). sected to. See 37 CFR 1.121(d).			
Priority under 35 U.S.C. § 119					
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>					
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 3/31/06.	4)  Interview Summary Paper No(s)/Mail Da 5)  Notice of Informal P 6)  Other:	nte			

#### DETAILED ACTION

#### Election/Restrictions

Applicant's election with traverse of Group II (claims 13-21) and the following species

Bioreactor vessel: aeration tank

Substrate: water of industrial origin

Living cells: bacteria

in the replies filed on 7/29/08 and 11/28/08 is acknowledged. The traversal is on the ground(s) that the prior art does not teach a means carrying out transfers of cell back to a bioreactor vessel. Applicants argue that the previously cited art is not an automatic device according to the present invention.

Applicants arguments have been considered but are not found persuasive.

It is noted that PCT Rule 13.2 defines "special technical features" as "those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art." Section 1850 of the MPEP states that the contribution over the prior art should be considered with respect to novelty and inventive step. As discussed in detail below, WO 00/34433 (as cited in IDS 3/31/06; since WO 00/34433 is not in English the English equivalent US 6,686,194 will be relied upon and referred to herein) teach the automatic selection device of the instant invention. In fact, Figure 3 and example 1 of the instant application expressly refer to WO 00/34433. Since WO 00/34433 render obvious the use of a bioreactor with the automatic selection device there is no contribution over the prior art with respect to an

inventive step. Thus the technical features are not a contribution over the prior art and the claims lack unity.

The requirement is still deemed proper and is therefore made FINAL.

In the instant case, the elected species were found in the prior art. Any art that was uncovered in the search for the elected species that reads on non-elected species is also cited herein.

Claims 22-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in the reply filed on 7/29/08 and 11/28/08.

Claims 1-12 have been cancelled.

Claims 13-21 are under consideration.

#### **Drawings**

Figure 3 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

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It is noted that page 14 states that Figure 3 represents a view of a selection device described in WO 00/34433. As such, Figure 3 is Prior Art.

# **Specification**

The disclosure is objected to because of the following informalities:

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

## Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
  - (1) Field of the Invention.
  - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (1) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

In the instant case, the specification does not include the section heading 'Brief Description of the Drawings' (see MPEP section 608.01(f)).

Appropriate correction is required.

# Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 and dependent claims refers to a substrate. The specification (page 7 line 19-31) provides a definition of substrate. The definition states 'the term 'substrate' denotes a medium containing a compound the metabolic conversion of which is envisaged...'. It is noted that claim 19 uses the claim language 'a compound the metabolic conversion of which is envisaged' as well. However, the metes and bounds of the substrate are unclear. In particular, it is unclear which compounds have envisaged metabolic conversions and which compounds do not have envisaged metabolic conversions. The characteristics of a compound the metabolic conversion of which is envisaged is not clearly set forth. As such, there can be different interpretations as to whether or not a compounds metabolic conversion can be envisaged. Further, it is noted that claim 15c states 'a source of medium (substrate)'. The use of parentheses is confusing. It is unclear if the intent is to define medium to mean substrate or if the intent is to show that the medium is to be provided for the substrate.

Claim 14 uses the phrase 'such as'. Claim 15 uses that phrase 'such as'. Claim 19 uses the phrase 'such as' in two locations. The phrase "such as" renders the claim indefinite because it

is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 15 uses the phrase 'in particular'. Claim 18 uses the phrase 'in particular'. The phrase "in particular" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 17 uses the phrase 'for example'. The phrase "for example" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 13-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/34433 (as cited in IDS 3/31/06; since WO 00/34433 is not in English the English equivalent Mutzel et al US 6,686,194 will be relied upon and referred to herein).

Mutzel teach a method and device for selecting accelerated proliferation of living cells in suspension (title, abstract). Mutzel teach the apparatus for continuous, periodical, or conditional culture conditions as recited in instant claim 13. Mutzel teach that the organisms used (title, abstract, claim 1,12, column 3 lines 54-60) can be prokaryotic or eukaryotic and specifically teach bacteria (column 3 line 65 for example) as recited in the instant claims, specifically claim 20. Mutzel teach that a recognized problem in the art is the lack of permanent proliferation of organisms in suspension and that previous techniques select static variants (column 1 lines 36-55). Mutzel teach that the present invention describes an automated genetics method which selects against static variants and prefers dynamic variants (column 2 lines 44-48, column 4 lines 39-42) as recited in claim 13b. Mutzel teach industrial application specifically for metabolizing chemical products such as environmental pollutants (column 2 lines 54-67) as recited in claim 19. In figures 1-16 and column 4 lines 4-42 Mutzel teach the components of the automatic device. Briefly, Mutzel teach 2 vessels (claim 1a and 4,6 of the figures) as recited in claim 14,15a; a system for connecting to culture vessels for sterilization or gas or substrate (claim 1e and 12,18,20-21 of the Figures) as recited in claim 14,15b-d; a system for connecting the devices (claim 1f) as recited in claim 14,15e; an outlet source to another device or bin (claim 4, 36 of the figures) as recited in claim 14. Specifically, Mutzel teach vessels (4,6), gas supply (12), medium source (18), sterilizing agent source (20-21), connecting conduits (22,24,30-32) which are described as valves (column 4 line 38, claim 2) and teach a conduit (36) for discharging the

culture (column 4 lines 30-34, claim 4). It is noted that the valves taught by Mutzel are interpreted as means for connecting as recited in claim 15e. Mutzel teach that the selection is of living cells in suspension (claim 12) as in claim 16 of the instant invention. In claim 12 Mutzel teach the steps of claim 18 of the instant invention. Further, it is noted that claim 18 states that the suspension 'can in particular be', thus it is not required to operate in the recited fashion.

Mutzel does not expressly teach in a single embodiment a bioreactor connected to the selection device.

Mutzel teach that a recognized problem in the art is the lack of permanent proliferation of organisms in suspension and that previous techniques select static variants (column 1 lines 36-55). Mutzel teach that the present invention describes an automated genetics method which selects against static variants and prefers dynamic variants (column 2 lines 44-48,column 4 lines 39-42). Mutzel teach industrial application specifically for metabolizing chemical products such as environmental pollutants (column 2 lines 54-67) as recited in claim 19. Since Mutzel teach applications for metabolizing chemical products one would be motivated to use the selection device in such applications. In other words, one would be motivated to use the selection device in particular applications based on the express suggestions of Mutzel (column 2 line 54-67) and the recognized problem in the art (column 1 lines 36-55). Since Mutzel teach metabolizing chemical products one would use the appropriate bacteria to metabolize the products. In order to carry out such application one would connect the selection device of Mutzel with the appropriate vessel/tank that holds the bacteria and chemical products as recited in claim 17. In fact, Mutzel recognize the use of culture vessels (column 1 line 15). More specifically, Mutzel specifically

teach means making it possible for (see 36 of the figure and column 4 lines 35-42) transferring the cells from the selection device to the vessel/tank. In carrying out such method one would transfer cells from the vessel/tank to the automation device and then use the selection system of Mutzel to eliminate static cells and transfer the dynamic cells to the vessel/tank as recited in instant claim 13. Since Mutzel teach periodic use of the selection system (claim 16) and teach that a recognized problem in the art is the lack of permanent proliferation of organisms in suspension and that previous techniques select static variants (column 1 lines 36-55) one would be motivated to periodically carry out the transfer of cells as recited in claim 21. It is noted that claim 21 recites 'at least once a week'. Carrying out the process once meets the limitation of once a week.

Since Mutzel teach that the present invention describes an automated genetics method which selects against static variants and prefers dynamic variants (column 2 lines 44-48, column 4 lines 39-42) one would have a reasonable expectation of success. Since Mutzel teach industrial application specifically for metabolizing chemical products such as environmental pollutants (column 2 lines 54-67) one would have a reasonable expectation of success in carrying out such methods.

In the instant case, all the claimed elements (briefly, the selection device of Figure 1 and claim 1 of Mutzel, and the culture vessels required for metabolizing chemical products such as environmental pollutants (column 2 lines 54-67)) were known in the art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions and the combinations would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

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Although unclear (see 112 2<sup>nd</sup>) the 'substrate' has been given the broadest reasonable interpretation to include any types of compound. Although unclear (see 112 2<sup>nd</sup>) the phrase 'a source of medium (substrate)' has been given the broadest reasonable interpretation to mean either a medium or a substrate. Although unclear (see 112 2<sup>nd</sup>) the phrases 'such as', 'in particular', and 'for example' have been interpreted as non-limiting phrases.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference.

Claims 13-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/34433 (as cited in IDS 3/31/06; since WO 00/34433 is not in English the English equivalent US 6,686,194 will be relied upon and referred to herein) and Hawkins (US 5,624,563).

As discussed in detail above, Mutzel teach a method and device for selecting accelerated proliferation of living cells in suspension (title, abstract). Mutzel teach the apparatus for continuous, periodical, or conditional culture conditions as recited in instant claim 13. Mutzel teach that the organisms used (title, abstract, claim 1,12, column 3 lines 54-60) can be prokaryotic or eukaryotic and specifically teach bacteria (column 3 line 65 for example) as recited in the instant claims, specifically claim 20. Mutzel teach that a recognized problem in the art is the lack of permanent proliferation of organisms in suspension and that previous techniques select static variants (column 1 lines 36-55). Mutzel teach that the present invention describes an automated genetics method which selects against static variants and prefers dynamic variants

(column 2 lines 44-48, column 4 lines 39-42) as recited in claim 13b. Mutzel teach industrial application specifically for metabolizing chemical products such as environmental pollutants (column 2 lines 54-67) as recited in claim 19. In figures 1-16 and column 4 lines 4-42 Mutzel teach the components of the automatic device. Briefly, Mutzel teach 2 vessels (claim 1a and 4,6 of the figures) as recited in claim 14,15a; a system for connecting to culture vessels for sterilization or gas or substrate (claim 1e and 12,18,20-21 of the Figures) as recited in claim 14,15b-d; a system for connecting the devices (claim 1f) as recited in claim 14,15e; an outlet source to another device or bin (claim 4, 36 of the figures) as recited in claim 14. Specifically, Mutzel teach vessels (4,6), gas supply (12), medium source (18), sterilizing agent source (20-21), connecting conduits (22,24,30-32) which are described as valves (column 4 line 38, claim 2) and teach a conduit (36) for discharging the culture (column 4 lines 30-34, claim 4). It is noted that the valves taught by Mutzel are interpreted as means for connecting as recited in claim 15e. Mutzel teach that the selection is of living cells in suspension (claim 12) as in claim 16 of the instant invention. In claim 12 Mutzel teach the steps of claim 18 of the instant invention. Further, it is noted that claim 18 states that the suspension 'can in particular be', thus it is not required to operate in the recited fashion.

Mutzel does not expressly teach the elected species of aeration tank as the bioreactor and water of industrial origin as the substrate.

Mutzel teach that a recognized problem in the art is the lack of permanent proliferation of organisms in suspension and that previous techniques select static variants (column 1 lines 36-55). Mutzel teach that the present invention describes an automated genetics method which

selects against static variants and prefers dynamic variants (column 2 lines 44-48, column 4 lines 39-42). Since Mutzel teach industrial applications (column 2 lines 54-67) one would be motivated to use the device of Mutzel for various applications.

Hawkins teach a process and apparatus for treatment of wastewater (title, abstract, claims). Hawkins teach the use of organisms specifically bacteria for use in wastewater treatment (column 1 lines 24-29). Hawkins teach that lagoons (columns 1-2 connecting paragraph) or tanks (column 2 lines 40-60) are used for wastewater treatment as recited in instant claim 17. Hawkins recognize the use of aeration (abstract, column 3 lines 53-59). Hawkins teach that maintaining proper concentration of bacteria and insuring the continuous presence of bacteria are often goals of wastewater treatment and recognize that the changing bacterial environment may be undesirable to the process (column 3 lines 40-60). As such, Hawkins recognize what is well known in the art – that bacteria are useful for wastewater treatment and that various phases of treatment (see Figure 2) are often carried out during wastewater treatment. Further, Hawkins recognize that a problem in the art is that the bacteria are not always adapted to the culture conditions. Since Mutzel teach methods in which variants are selected that 'are always better adapted to the culture conditions' (column 2 lines 44-48) one would be motivated to use the device of Mutzel to improve the wastewater treatment process described by Hawkins. In addition to applications involving metabolizing chemical products such as environmental pollutants (column 2 lines 54-67) one would recognize the utility of the device and method of Mutzel for other applications such as in wastewater treatment.

Taken together one would be motivated to use the selection device in particular applications based on the express suggestions of Mutzel (column 2 line 54-67) and the

recognized problem in the art (column 1 lines 36-55). Since Hawkins teach that maintaining proper concentration of bacteria during wastewater treatment and insuring the continuous presence of bacteria are often goals of wastewater treatment and recognize that the changing bacterial environment may be undesirable to the process (column 3 lines 40-60) one would be motivated to use the method and device of Mutzel. In order to carry out such application one would use the wastewater system of Hawkins which includes the appropriate tanks and bacteria and couple the system to the device of Mutzel. Since Mutzel specifically teach means making it possible for (see 36 of the figure and column 4 lines 35-42) transferring the cells from the selection device one would be motivated to remove cells from the wastewater system, use the selection device of Mutzel and transfer the cells back to the wastewater system. In carrying out such method one would transfer cells from the wastewater system to the automation device and then use the selection system of Mutzel to eliminate static cells and transfer the dynamic cells to the vessel/tank as recited in instant claim 13. Taken together the references obviate the use of the elected species as claimed. Since Mutzel teach periodic use of the selection system (claim 16) and teach that a recognized problem in the art is the lack of permanent proliferation of organisms in suspension and that previous techniques select static variants (column 1 lines 36-55) one would be motivated to periodically carry out the transfer of cells as recited in claim 21. It is noted that claim 21 recites 'at least once a week'. Carrying out the process once meets the limitation of once a week.

Since Mutzel teach that the present invention describes an automated genetics method which selects against static variants and prefers dynamic variants (column 2 lines 44-48, column 4 lines 39-42) one would have a reasonable expectation of success. Since Mutzel teach industrial

applications (column 2 lines 54-67) one would have a reasonable expectation of success in carrying out such methods.

In the instant case, all the claimed elements (briefly, the selection device of Figure 1 and claim 1 of Mutzel, and the wastewater system of Hawkins) were known in the art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions and the combinations would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Although unclear (see 112 2<sup>nd</sup>) the 'substrate' has been given the broadest reasonable interpretation to include any types of compound. Although unclear (see 112 2<sup>nd</sup>) the phrase 'a source of medium (substrate)' has been given the broadest reasonable interpretation to mean either a medium or a substrate. Although unclear (see 112 2<sup>nd</sup>) the phrases 'such as', 'in particular', and 'for example' have been interpreted as non-limiting phrases.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference.

### Relevant Prior Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: US 2005/0115892 (and non-English equivalent FR 2836910, both cited in IDS 3/31/06) teach treating sludge (claim 1) via a bioreactor (Figure 1) using bacteria or yeasts for

example (section 0022) and teach process automation (section 0086). Any rejection using US 2005/0115892 would be duplicative of the rejections set forth herein.

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD T. NIEBAUER whose telephone number is (571)270-3059. The examiner can normally be reached on Monday-Thursday, 7:30am-5:00pm, alt. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Anish Gupta/ Primary Examiner, Art Unit 1654 Application/Control Number: 10/574,197

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